UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,143	05/06/2004	Jayant Ekanth Khanolkar	9626	7415

27752 7590 04/14/2010

THE PROCTER & GAMBLE COMPANY
Global Legal Department - IP
Sycamore Building - 4th Floor
299 East Sixth Street
CINCINNATI, OH 45202

EXAMINER	
PALENIK, JEFFREY T	
ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
04/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/840,143	KHANOLKAR ET AL.	
	Examiner	Art Unit	
	Jeffrey T. Palenik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-12 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-12 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

STATUS OF THE APPLICATION

Receipt is acknowledged of Applicants' Amendments and Remarks filed, 15 January 2010 in the matter of Application N° 10/840,143. Said filings are entered on the record. The Examiner further acknowledges the following:

No claims have been added or cancelled.

Claims 8 and 15 have been amended. It is noted that Claim 11 appears to have been amended in a non-compliant manner. Looking to the amendment filed on 5 June 2009, the phrase "of the composition" was amended in at that time and the claim properly indicated as being "(Currently Amended)". It thus appears that the underlined phrase in claim 11 was simply missed by Applicant and is thus *not* considered by the Examiner as constituting a non-compliant amendment.

Claims 8 and 15 have been amended to remove "propylene glycol laureates" and "diethylene monoethyl ethers", thereby narrowing the scope of the solvent limitations.

No new matter has been added.

Thus, claims 1-4, 6-12 and 14-17 continue to represent all claims currently under consideration.

INFORMATION DISCLOSURE STATEMENT

No new Information Disclosure Statement (IDS) have been submitted for consideration.

WITHDRAWN REJECTIONS

Rejection under 35 USC 112

Applicants' amendments to claims 8 and 15 are sufficient to render moot the rejection to claims made under 35 USC 112, second paragraph. Said rejection now stands **withdrawn**.

MAINTAINED REJECTIONS

The following rejections are maintained from the previous Office Correspondence dated 5 June 2009 since the art which was previously cited continues to read on the amended/newly cited limitations.

CLAIM REJECTIONS - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention [*emphasis added to reflect rejections which have been overcome*].

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim

indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3 and 12 recite the broader limitation of "antihistamines", and the claims also recite "non-sedating antihistamines" which is the narrower statement of the range/limitation.

RESPONSE TO ARGUMENTS

Applicants' remarks with regard to the indefiniteness rejection of claims 3 and 12 under 35 USC 112, second paragraph, have been fully considered but they are not persuasive.

Applicants argue that the rejected terms are "fully defined, described and exemplified in the present specification" and that "Applicants provide nonlimiting examples of "antihistamines" and "non-sedating antihistamines"". Applicants further state that based on the definitions, the two are clearly separate classes of actives.

In response, the Examiner respectfully submits that Applicants describe the two drug types in the disclosure as being "specific" examples, but also "non-limiting" examples of the two respective drug types. As the two categories are non-limiting, it follows that a case of indefiniteness is still present since the broader genus of antihistamines necessarily encompasses the narrower species of "non-sedating antihistamines".

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-12 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Dobrozsi et al. (US Pre-Grant Publication N° 2003/013377) and White (WO 94/25008) in further view of Kennedy (*The Thinking Person's Guide to Perfect Health: Chelation*).

The amended recitations of the base claims 1 and 11 are respectively directed to a soft gelatin-encapsulated pharmaceutical composition and a method of providing said composition. The Examiner broadly and reasonably interprets claim 11 as reciting the same subject matter as claim 1, particularly since the instantly claimed method recites the steps of "providing" the formulation of claim 1 and encapsulating said formulation in a soft gelatin capsule.

The instantly claimed encapsulated composition is recited as comprising: a.) about 55% to about 90% by weight of the composition of an active pharmaceutical ingredient, b.) about 0.001% to about 1.0% by weight of the composition of a stabilizing agent such as disodium EDTA, and c.) about 9% to about 39% by weight of the composition of a solvent.

The teachings of Dobrozsi are drawn to a the preparation of stable liquid pharmaceutical compositions containing concentrated levels of pharmaceutical active ingredients, in addition to hydrophilic solvents, water and compounds such as stabilizers ¶[0021]. Such end-use compositions or exact dosing measuring "devices" which are taught include liquid filled edible capsules. Soft gelatin capsules are specifically taught in Example 13. Each of the Examples teaches incorporating the stabilizer disodium EDTA in an amount ranging from 0.02-0.91 wt%, thereby also teaching the limitations of claims 4, 6 and 14. The hydrophilic solvents which are used include both polyethylene glycol and propylene glycol, wherein said solvents are present in amounts as low as about 30 percent by weight of the composition ¶¶[0044] and [0045]. Paragraph [0048] teaches the optional inclusion of additional ingredients such as antioxidants. The concentrated active ingredients are taught as comprising as much as about 40% by weight of the composition ¶[0034]. This is where Dobrozsi falls short of teaching the instantly claimed invention.

However, the teachings of White remedy this deficiency particularly since the invention is directed to a method for preparing pharmaceutical compositions, which preferably comprise from about 0.01% to about 50% by weight of a pharmaceutically active ingredient (claim 1; pg 8, lines 14-16). Claims 1 and 5 further expressly teach incorporating such hydrophilic solvent compositions as polyvinyl pyrrolidone (i.e. preferably 10-50% by weight PVP) and polyethylene glycol in amounts as high as 20% by weight. Claim 9 and Example VIII are expressly drawn to teachings whereby the active composition formed is encapsulated within a soft gelatin capsule. Further regarding Example VIII, the method expressly teaches heating and mixing PVP and polyethylene glycol (e.g. 20% w/w of the composition) prior to the adding the active ingredient (e.g. acetaminophen) to the solvent blend in the amount of 57.14% w/w of the composition. This creates a "supersaturated solution" wherein the majority of the drug remains in suspended form. The teachings of Example VIII are also considered by the Examiner as reading on the limitations recited by claim 2 wherein the active ingredient suspended within the capsule comprises "about 58% by weight of the composition". This limitation is interpreted in light of Applicants' specification (see MPEP §2111), particularly Sample 5 (pg. 10; Table), wherein the composition which is commensurate in scope with the limitations of claim 2 (e.g. about 58 wt%) dedicates 58.6 wt% to the pharmaceutically active compound. Though there is no lower limit expressly defined by Applicants for "about 58%", the Examiner broadly and reasonably interprets said limitation as encompassing amounts which are at within ± 1 wt% of this amount.

The invention of White is deficient such that no express teaching of a "stabilizing agent" is provided. However, similar to the teachings of Dobrozsi, White teaches that antioxidant compounds may be added to the formulation as optional ingredients (pg. 12, lines 31-33).

The limitations of claims 3 and 12 recite different categories of pharmaceutically active ingredients which may be suspended within the capsule formulation. The invention of Dobrozsi expressly teaches the use of compounds such as antihistamines, antitussives, expectorants/mucolytics, bronchodilators and decongestants ¶¶[0028]-[0033]. The invention of White expressly teaches using similar types of pharmaceutically active ingredients such as antitussives, antihistamines, decongestants, expectorants and analgesics (Claim 7).

The limitations of claims 7 and 10 recite that the overall composition further comprises about 0.1 wt% to about 5.0 wt% water. The invention to Dobrozsi expressly teaches this limitation wherein the formulations may also include water in amounts as low as about 5% by weight of the composition ¶[0046]. The formulations of White again expressly teach that the formulations may comprise water mixed with or in addition to polyethylene glycol and may also range from 0.1% to 20% by weight (claim 5).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to have incorporated a stabilizing agent such as disodium EDTA into a supersaturated active suspension such as the one which is taught by White. The ordinarily skilled artisan would have been highly motivated to do so particularly since Dobrozsi is expressly directed to the preparation of formulations wherein the active ingredients are more difficult to solubilize. Furthermore, higher concentrations of such actives not only increase the likely instability of the overall formulation, but also the likelihood for the precipitation and presence of contaminants as well ¶[0025]. As such, the invention of Dobrozsi seeks to stabilize

more concentrated formulations using compounds such as disodium EDTA. White, when considered in light of the teachings of Kennedy, is considered by the Examiner as teaching EDTA compounds as an optional ingredient which may be added to the suspension formulations. In particular, Kennedy generally teaches that EDTA may act as a powerful antioxidant in the presence of radical compounds (pg. 5, points 3 and 7). Thus, when considered in further view with the teachings of Dobrozsi, which *do* add disodium EDTA for the sake of stability of the formulation, it follows that the skilled artisan would again be highly motivated to add a powerful antioxidant such as EDTA to the formulation(s) of White, and expect to arrive at the instantly claimed invention.

Thus, based on the teachings of the combined references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, alone or in combination, especially in the absence of evidence to the contrary.

RESPONSE TO ARGUMENTS

Applicants' arguments with regard to the rejection of claims 1-4, 6-12 and 15-17 under 35 USC 103(a) as being unpatentable over the combined teachings of Dobrozsi et al. (US Pre-Grant Publication N° 2003/013377) and White (WO 94/25008) in further view of Kennedy (*The Thinking Person's Guide to Perfect Health: Chelation*) have been fully considered but they are not persuasive.

Applicants acknowledge on the record that the Dobrozsi reference was published on 19 June 2003, whereas the earliest effective filing date accorded to the instant application is 6 May 2004. Applicants traverse the rejection on the grounds that since the Dobrozsi reference "only qualifies as prior art under 35 USC §102(e)" and because the present application and Dobrozsi reference were commonly assigned to Proctor & Gamble Company at the time of the instant invention, that the Dobrozsi reference is unavailable as art under 35 USC §103(c).

In response, the Examiner respectfully disagrees and submits that the Dobrozsi reference is in fact available as prior art. The reference has a filing date of 10 October 2001 and a publication date of 19 June 2003. Since the publication does not fall more than a year before Applicants' earliest effective filing date, the reference is unavailable under 35 USC §102(b). However, since the publication date still falls *before the earliest effective filing date* of the application, the reference is still available under 35 USC §102(a), and thus available as a reference under 35 USC §103(a). In accordance with MPEP §2146, only references which qualify as prior art under 35 USC §102(e), (f), and/or (g), may be excluded under 35 USC §103(c). Since Dobrozsi is available under 35 USC §102(a), it cannot be excluded in this manner.

For these reasons, Applicants' arguments are found unpersuasive. Said rejection is therefore **maintained**.

All claims under consideration remain rejected; no claims are allowed.

CONCLUSION

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

CORRESPONDENCE

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey T. Palenik whose telephone number is (571) 270-1966. The examiner can normally be reached on 7:30 am - 5:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615